

# BALLOON CATHETER AND ITS MANUFACTURE

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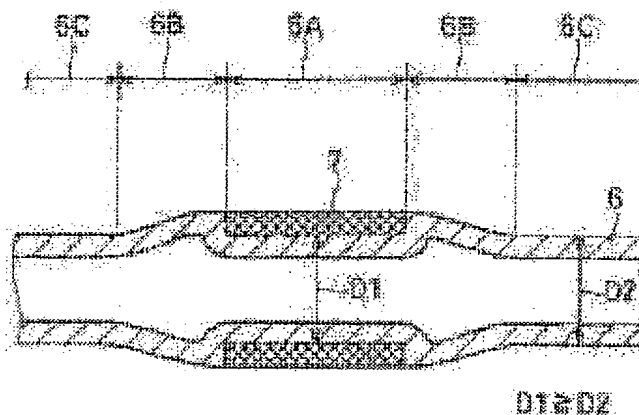
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**Abstract of JP 2000296179 (A)**

**PROBLEM TO BE SOLVED:** To prevent a tubular shaft from being damaged as the result of a decrease in the thickness of the tubular shaft by eliminating a step between a marker end and a tubular shaft mounting part at a marker mounting part, and either forming a marker-fixing groove in fixing a marker or reducing the diameter of an end for insertion of the tubular marker or to provide a balloon catheter of good flexibility by fixing the marker to the tubular shaft without requiring a contracting tube or adhesive to be used for a marker fixing member. **SOLUTION:** A marker 7 is buried in a tubular shaft 6 on each side of the marker 7 by expanding the tubular shaft 6, the outside diameter D1 of the tubular shaft 6 at its attaching part 6A for the marker 7 being equal to or greater than the outside diameter D2 of a tubular shaft part 6C other than a clamping part 6B for the marker 7. By adopting such a structure, the tubular shaft 6 at its attaching part 6A for the marker 7 can be made thinner than those of the prior art, and the tubular shaft 6 can be prevented from being broken at the attaching part 6A for the marker 7.



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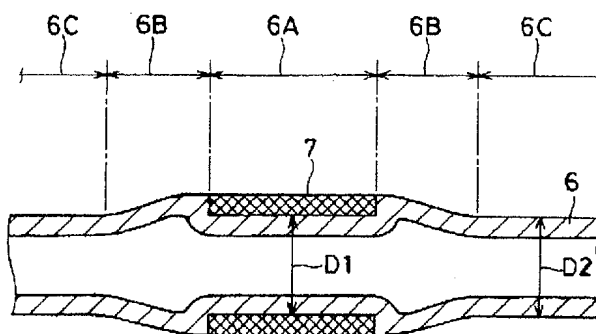
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(54) 【発明の名称】 バルーンカテーテルおよびその製造方法

(57) 【要約】

【課題】 従来の技術では、マーカーの装着部位における管状シャフトの外径を、他の部位より小さくしてマーカーを管状シャフトに嵌め込み、マーカーと拡張バルーンとの接触を抑えていたが、マーカーの装着部位における管状シャフトが薄くなるため、管状シャフトがマーカーの装着部位で破損しやすくなる不具合があった。

【解決手段】 マーカー7は、マーカー7の両側の管状シャフト6を拡張させて管状シャフト6に埋め込ませたものであり、マーカー7の装着部位6Aにおける管状シャフト6の外径D1は、マーカー7の挟持部位6B以外の管状シャフト部位6Cの外径D2以上に設けられている。このような構造を採用することにより、従来技術に比較してマーカー7の装着部位6Aにおける管状シャフト6を厚くでき、管状シャフト6がマーカー7の装着部位6Aで破損する不具合を回避できる。

 $D1 \geq D2$

## 【特許請求の範囲】

【請求項 1】 拡張バルーンの内にある管状シャフトの外周面上に X 線不透過マーカーを有するバルーンカテーテルにおいて、

前記マーカーは、そのマーカーの両側の前記管状シャフトに挟まれて前記管状シャフトに固定されるとともに、前記マーカーの装着部位における前記管状シャフトの外径は、前記マーカーを挟持する部位以外における前記管状シャフトの外径以上に設けられたことを特徴とするバルーンカテーテル。

【請求項 2】 請求項 1 のバルーンカテーテルにおいて、前記マーカーは、巻線コイルよりなり、前記マーカーの装着部位における前記管状シャフトの外周面は、前記巻線コイルの線材と線材との間の谷部に進入することを特徴とするバルーンカテーテル。

【請求項 3】 請求項 1 または請求項 2 のバルーンカテーテルは、前記管状シャフトが熱可塑性樹脂よりなり、前記マーカーの装着部位における前記管状シャフト、あるいは前記マーカーの装着部位とその周辺部位の前記管状シャフトを軟化点から溶点までの間の温度に昇温させる昇温工程と、前記管状シャフトに拡張力を与える管径拡張工程と、の組み合わせによって製造されることを特徴とするバルーンカテーテルの製造方法。

【請求項 4】 請求項 1 または請求項 2 のバルーンカテーテルは、前記管状シャフトが架橋された樹脂よりなり、この架橋された樹脂よりなる前記管状シャフトを延伸し、前記管状シャフトの外径を前記マーカーの内径寸法以下に小径化させる管状シャフト延伸工程と、この管状シャフト延伸工程で小径化された前記管状シャフトに前記マーカーを装着し、このマーカーの装着部位における前記管状シャフト、あるいは前記マーカーの装着部位とその周辺部位の前記管状シャフトを形状復帰温度に昇温させる昇温工程と、によって製造されることを特徴とするバルーンカテーテルの製造方法。

## 【発明の詳細な説明】

## 【0001】

【発明の属する技術分野】 本発明は、医療用のバルーンカテーテルに関するものであり、特に管状シャフトに固定される X 線不透過マーカーの固定技術に関する。

## 【0002】

【従来の技術】 従来、この種の技術として、特開平 8-289934 号公報に開示された技術が知られている。この技術は、図 14 に示すように、マーカー J3 の装着部位 J1 における管状シャフト外径 J1 d を、他の部位 J2 の管状シャフト外径 J2 d より小さくしてマーカー J3 を管状シャフト J4 に嵌め込み、マーカー J3 を固定するか管状シャフト J4 のマーカー取り付け部より先端部を管状マーカー J3 が挿入可能に細く加工し、マーカー J3 を挿入後、マーカー J3 を収縮チューブにより

固定している。また、上記発明以外の方法として、マーカー J3 を管状シャフト J4 に接着剤を用いて固定している。

## 【0003】

【発明が解決しようとする課題】 しかし、上記公報に示される技術では、マーカー J3 を管状シャフト J4 に嵌め込むために、マーカー J3 の装着部位 J1 における管状シャフト外径 J1 d を、他の部位 J2 の管状シャフト外径 J2 d より小さくしているため、マーカー J3 の装着部位 J1 における管状シャフト J4 の厚みが薄くなり、マーカー J3 の装着部位 J1 (特にマーカー J3 の角部付近) において管状シャフト J4 が破損する可能性が高くなってしまふ。また、管状シャフト J4 にマーカー J3 を固定するのに収縮チューブによる、あるいは接着剤によるのはマーカー固定材層がマーカー部にでき、この部の屈曲性を悪くすると同時にマーカー取り付けに

## 【0004】

【発明の目的】 本発明は、上記の事情に鑑みてなされたもので、その目的は、マーカーの取り付け部において、マーカー端部と管状シャフトの取り付け部の段差をなくすとともに、マーカーの固定にマーカー固定用の溝の形成、あるいは管状マーカー挿入のための先端部の細径化により、管状シャフトの厚みが薄くなることによる管状シャフトの破損を防ぎ、あるいはまた、マーカー固定材に収縮チューブの使用、または接着剤の使用を必要としないで、マーカーを管状シャフトに固定することにより屈曲性の良いバルーンカテーテルの提供にある。マーカーの装着部位における管状シャフトの厚みが薄くなるのを防いで管状シャフトの破損を防ぐことのできるバルーンカテーテルの提供にある。

## 【0005】

【課題を解決するための手段】 【請求項 1 の手段】 拡張バルーンの内にある管状シャフトの外周面上に X 線不透過マーカーを有するバルーンカテーテルにおいて、前記マーカーは、そのマーカーの両側の前記管状シャフトに挟まれて前記管状シャフトに固定されるとともに、前記マーカーの装着部位における前記管状シャフトの外径は、前記マーカーを挟持する部位以外における前記管状シャフトの外径以上に設けられたことを特徴とする。

【0006】 【請求項 2 の手段】 請求項 1 のバルーンカテーテルにおいて、前記マーカーは、巻線コイルよりなり、前記マーカーの装着部位における前記管状シャフトの外周面は、前記巻線コイルの線材と線材との間の谷部に進入することを特徴とする。

【0007】 【請求項 3 の手段】 請求項 1 または請求項 2 のバルーンカテーテルは、前記管状シャフトが熱可塑性樹脂よりなり、前記マーカーの装着部位における前記管状シャフト、あるいは前記マーカーの装着部位とその周辺部位の前記管状シャフトを軟化点から溶点までの間

の温度に昇温させる昇温工程と、前記管状シャフトに拡張力を与える管径拡張工程と、の組み合わせによって製造されることを特徴とする。

【0008】〔請求項4の手段〕請求項1または請求項2のバルーンカテーテルは、前記管状シャフトが架橋された樹脂よりなり、この架橋された樹脂よりなる前記管状シャフトを延伸し、前記管状シャフトの外径を前記マーカの内径寸法以下に小径化させる管状シャフト延伸工程と、この管状シャフト延伸工程で小径化された前記管状シャフトに前記マーカを装着し、このマーカの装着部位における前記管状シャフト、あるいは前記マーカの装着部位とその周辺部位の前記管状シャフトを形状復帰温度に昇温させる昇温工程と、によって製造されることを特徴とする。

【0009】

【発明の作用および効果】〔請求項1の作用および効果〕マーカの装着部位における管状シャフトの外径が、従来の技術に比較して大きく設けられたことにより、マーカの装着部位における管状シャフトの厚みが従来の技術に比較して厚く、結果的にマーカの装着部位における管状シャフトの破損を防ぐことができる。また、マーカは、そのマーカの両側の管状シャフトに挟まれて管状シャフトに固定されるため、マーカの両側端部に管状シャフトが存在する構造になる。このため、マーカの外側角部と拡張バルーンとの接触が、マーカを挟持する管状シャフトの挟持部位によって抑えられ、結果的に拡張バルーンの破損を防ぐことができる。

【0010】〔請求項2の作用および効果〕マーカを巻線コイルによって設けたことにより、管状シャフト曲折時にマーカが装着された部位においてマーカおよび管状シャフトの曲折が可能になり、管状シャフトの応動性が高まる。そして、マーカの装着部位における管状シャフトの外周面が巻線コイルの線材と線材との間の谷部に進入しているため（言い換えると、管状シャフトの外周面が巻線コイルの線材と線材との間に食い込んでいるため）、管状シャフトとマーカとが強固に固着される。

【0011】〔請求項3の作用および効果〕管状シャフトとして熱可塑性樹脂を用い、マーカを装着した部位の管状シャフトを昇温工程で軟化点～溶点の間の温度に加熱するとともに、管径拡張工程で管状シャフトに拡張力を与えることにより、加熱されて熱が伝わった部位の管状シャフトが膨らむ。つまり、マーカの内側およびマーカの両端部分の管状シャフトが膨らみ、マーカは、そのマーカの両側の管状シャフトに挟まれるとともに、マーカの装着部位における管状シャフトの外径が、マーカを挟持する部位以外における管状シャフトの外径以上になる。このように、請求項1または請求項2のバルーンカテーテルを製造することができる。

【0012】〔請求項4の作用および効果〕管状シャフトとして架橋された樹脂を用い、管状シャフト延伸工程によって管状シャフトを延伸し、管状シャフトの外径をマーカの内径寸法以下に小径化させる。次に、マーカを装着した部位の管状シャフトを昇温工程で昇温させ、昇温した部位の管状シャフトを延伸前の形状に復帰させる。つまり、マーカの内側およびマーカの両端部分の管状シャフトが膨らみ、マーカは、そのマーカの両側の管状シャフトに挟まれるとともに、マーカの装着部位における管状シャフトの外径が、マーカを挟持する部位以外における管状シャフトの外径以上になる。このように、請求項1または請求項2のバルーンカテーテルを製造することができる。

【0013】

【発明の実施の形態】本発明の実施の形態を、複数の実施例を用いて説明する。

〔第1実施例〕図1～図9は第1実施例を示すもので、まず図8、図9を用いてバルーンカテーテルを用いた治療器具を説明する。この治療器具1は、血管末梢側血流検査、血管内狭窄部の拡張治療、血管内の血流調節等に利用されるもので、治療や検査箇所への案内を目的として血管内に最初に挿入されるガイドワイヤ2と、このガイドワイヤ2に沿わせて血管内に挿入されるガイドカテーテル3と、このガイドカテーテル3内に挿入されて治療や検査箇所の近くまで案内されるとともに、ガイドワイヤ2に沿って治療や検査箇所へ案内されるバルーンカテーテル4とからなる。

【0014】このバルーンカテーテル4は、患部拡張用の拡張バルーン5Aを備えた外管5と、この外管5の内部に配置されるとともに、ガイドワイヤ2が内部に挿通される管状シャフト6とからなり、外管5と管状シャフト6は管の長手方向にずれないように同軸的に固定されている。なお、拡張バルーン5Aは、バルーンカテーテル4の手元側に設けられたインデフレーター4Aによって、拡張および収縮の操作が行われる。拡張バルーン5Aの内側における管状シャフト6の周囲には、X線で拡張バルーン5Aの位置を確認するためのX線不透過マーカ7が1つ、あるいは複数固着されている。なお、図9では、拡張バルーン5Aの内側における管状シャフト6の周囲に2つのマーカ7が装着された例を示す。

【0015】この実施例に示す管状シャフト6は、熱可塑性樹脂を用いたものであり、熱可塑性樹脂の一例として、ポリエチレン、ポリプロピレン、ポリオレフィン、ポリ塩化ビニル、ポリアミドエラストマー、ポリウレタン等を用いたものである。この実施例に示す外管5も、管状シャフト6と同様、熱可塑性樹脂を用いたものであり、熱可塑性樹脂の一例として、ポリエチレン、ポリプロピレン、ポリオレフィン、ポリ塩化ビニル、ポリアミドエラストマー、ポリウレタン等を用いたものである。

【0016】この実施例に示すマーカ7は、X線不透

過金属製の筒体を用いたものであり、X線不透過金属の一例として、白金、金、タングステン、これらの合金、白金とイリジウムの合金、銀とパラジウムの合金等を用いたものである。また、マーカー7の厚みは段差を小さくする意味合いからは薄いほうが望ましいが、X線を不透過して位置確認に用いる意味合いからは厚いほうが望ましく、少なくとも100 $\mu$ m以上の厚みに設けられている。

【0017】このマーカー7は、図1に示すように、マーカー7周辺の管状シャフト6に埋め込まれて、マーカー7と管状シャフト6の表面の段差がなくされており、マーカー7の両側の管状シャフト6に挟まれて管状シャフト6に固定されるとともに、マーカー7の装着部位6Aにおける管状シャフト6の外径D1は、マーカー7を挟持する挟持部位6B以外における管状シャフト部位6Cの外径D2以上に設けられている。マーカー7の両側においてマーカー7を両側から挟む管状シャフト6の挟持部位6Bは、管状シャフト6の塑性変形によって形成されたものであり、その製造方法の一例を図2～図7を用いて説明する。

【0018】まず、図2(a)に示すように、上記で示した熱可塑性樹脂よりなる管状シャフト6の所定部位(マーカー設置部位)に、上記で示したマーカー7を配置する。次に、マーカー7の外側に配置した加熱手段8(図6参照)によって、マーカー7の装着部位6Aにおける管状シャフト6を軟化点から溶点までの間の温度に昇温させる(昇温工程)。この昇温工程によってマーカー7の装着部位6Aの管状シャフト6温度が管状シャフト6の軟化点から溶点までの間の温度に昇温するとともに、熱の伝達によってマーカー7の周辺の管状シャフト6も軟化点から溶点までの間の温度に昇温する。

【0019】次に、管状シャフト拡張手段によって少なくともマーカー7が装着された部位の管状シャフト6に拡張力を与える(管径拡張工程)。この管径拡張工程によって、加熱手段8によって軟化した部分の管状シャフト6が外側に拡張し、結果的に図1に示したように、マーカー7は両側の管状シャフト6に挟まれるとともに、マーカー7の装着部位6Aにおける管状シャフト6の外径D1がマーカー7を挟持する部位6B以外における管状シャフト部位6Cの外径D2以上になる。その後、冷却手段による強制冷却や放熱による自然冷却によって昇温された管状シャフト6の温度が軟化点より下がることによって、管状シャフト6が塑性変形した形状で固まり、管状シャフト6の所定部位にマーカー7が強固に固定される。

【0020】なお、上記では、昇温工程を開始した後に管径拡張工程を開始した例を示したが、逆に管径拡張工程を開始した後に昇温工程を開始しても良いし、昇温工程と管径拡張工程を同時に開始しても良い。加熱手段8の一例として通電等によって発熱するリング状加熱手段

を例に示したが、熱風を付与する熱風加熱手段など、他の手段によって昇温させても良い。

【0021】また、図2では、マーカー7の一例として、外径長の長さと同径長の長さが等しく、端面が管長に対して直角のマーカー7を例に示したが、図3、図4に示すように、外径長の長さより内径長を短くして、マーカー7の端面を内側に傾斜させるとともに、外側端面を円弧等の面取りを施しても良い。このようにマーカー7の端面を内側に傾斜させるとともに、外側端面に面取りを施すことにより、マーカー7の端面と管状シャフト6の表面との段差を無くすることが容易に実施できるようになる。

【0022】一方、管状シャフト6の材料として、ナイロン、ポリアミド、ポリエステル等の結晶高分子材料を使用する場合、少なくともマーカー7の取付部分は管状シャフト6の成形時に延伸による結晶配向を行って強度を上げておくと良い。これによって、昇温、拡張によって管状シャフト6が延伸、変形しても管状シャフト6の変形部位の強度低下を防ぐことができる。また、管状シャフト6の材料として、ポリエチレン等の線状高分子材料を使用する場合、管状シャフト6の成形時に架橋剤を添加しておき、加熱架橋によって網状構造として強度を向上させるか、管状シャフト6の成形後に電子線放射により分子内にラジカルを発生させて強化させるか、あるいはマーカー7を管状シャフト6に装着した後に加熱処理や電子線照射処理を施して強度を向上させておくと良い。これによって、マーカー7の取付部分に、曲折、押しつぶし、振じり等の負荷が加わっても、マーカー7の取付部分の管状シャフト6が破損する不具合がない。

【0023】より具体的な製造方法の実施例を、図5～図7を用いて説明する。熱可塑性ポリアミド系樹脂であるナイロン12を、まず外径0.75mm、内径0.5mmのチューブ状に仮り押し出し形成する。次に、このチューブに、図5に示すように外径0.46mmのステンレス鋼線Sを挿入し、次いで150℃に加熱した内径0.56mmのダイスDに通し、延伸加工を施す。これによって、管状シャフト6が製造される。管状シャフト6をなすナイロンは、延伸加工によってその結晶は配向される。この際、管状シャフト6の延伸による応力除去のためにアニール処理を行う。この例では、外径0.56mm、内径0.46mm、肉厚0.5mmの管状シャフト6を製作した。

【0024】次に、管状シャフト6の所定部位(マーカー設置部位)にX線不透過な金属よりなる筒状のマーカー7を配置する。この場合のマーカー7は、管状シャフト6に挿通可能なもので、外径0.66mm、内径0.56mm、肉厚0.5mm、長さ1mmのものをを用いた。次に、少なくともマーカー7が装着された部位の管状シャフト6に拡張力を与える。この実施例における管状シャフト拡張手段は、図6に示すように、管状シャフ

ト6の内部を加圧するものであり、管状シャフト6の一端は予め熱封着や接着剤等により閉塞しておく。そして、図示しない加圧ポンプを管状シャフト6の他端に接続し、管状シャフト6の内部を空気によって加圧する（管径拡張工程）。

【0025】次に、マーカー7の外側に配置した加熱手段8（環状の加熱ヒータ）によって、マーカー7の装着部位6Aにおける管状シャフト6を軟化点から溶点までの間の温度に昇温させる（昇温工程）。管径拡張工程と昇温工程とによって、加熱されて軟化した部分の管状シャフト6が外側に拡張し、マーカー7は拡張した管状シャフト6の表面に埋没する。その後、放熱等によって管状シャフト6の温度が軟化点より下がることによって、管状シャフト6が塑性変形した形状で固まり、図7に示すようにマーカー7が管状シャフト6に固定される。

【0026】管状シャフト6の拡張がマーカー7の外径を越えると、マーカー7と管状シャフト6との接続部分の表面に段差が生じてしまうため、管状シャフト6の過拡張を防ぐために、この実施例では、管状シャフト6およびマーカー7の周囲に管径加工治具9を配置して管径拡張工程と昇温工程を実施した。この管径加工治具9は、例えば耐熱ガラス管よりなるもので、内径がマーカー7の外径とほぼ同じに設けられている。この管径加工治具9を用いることにより、管状シャフト6の過拡張が防がれ、マーカー7と管状シャフト6との接続部分の表面に段差が生じる不具合を確実に防ぐことができる。

【0027】〔実施例の効果〕マーカー7の装着部位6Aにおける管状シャフト6の外径D1は、マーカー7の挟持部位6B以外における管状シャフト部位6Cの外径D2以上に設けられている。つまり、マーカー7の装着部位6Aにおける管状シャフト6の外径D1は、従来の技術に比較して大きい。これによって、マーカー7の装着部位6Aにおける管状シャフト6の厚みが従来の技術に比較して厚くでき、結果的にマーカー7の装着部位6Aにおける管状シャフト6の破損を防ぐことができる。また、マーカー7は、そのマーカー7の両側の管状シャフト6に挟まれて管状シャフト6に固定され、マーカー7と管状シャフト6との表面の段差が無くされている。一方、マーカー7の管状シャフト6への固定にマーカー7の外側より収縮チューブによる固定、あるいは接着剤による固定の必要がないので、マーカー部のこれ等固定材による屈曲に対する抵抗がなく、かつマーカー7の端部と管状シャフト6の取り付け部の段差もなく、平滑にマーカー部を作成することができた。

【0028】〔第2実施例〕図10、図11を用いて第2実施例を説明する。上記の第1実施例では、マーカー7を管状シャフト6に固定する際、管状シャフト6の内部を加圧して管状シャフト6を拡張する手段を示したが、この第2実施例では管状シャフト6の外部を減圧して管状シャフト6を拡張する手段を示す。管状シャフト

6は、第1実施例と同様、一端は予め熱封着や接着剤により閉塞しておく。そして、管状シャフト6の所定部位（マーカー設置部位）にX線不透過な金属よりなる筒状のマーカー7を配置する。これを、減圧加工用の耐熱ガラス加熱固定治具10の内部に挿入する。この耐熱ガラス加熱固定治具10は、耐熱ガラスよりなるチューブで、その内径は管状シャフト6の過膨張を防ぐためにマーカー7の外径にほぼ一致した寸法に設けられている。

【0029】管径拡張工程では、耐熱ガラス加熱固定治具10の端部（管状シャフト6を挿入する開口端）における耐熱ガラス加熱固定治具10と管状シャフト6との間をゴム密閉栓11で閉塞した状態で、図示しない減圧ポンプによって耐熱ガラス加熱固定治具10の内部を減圧する。そして、マーカー7の外側に配置した加熱手段8（環状の加熱ヒータ）によって、マーカー7の装着部位6Aにおける管状シャフト6を軟化点から溶点までの間の温度に昇温させる。これにより、第1実施例と同様、加熱されて軟化した部分の管状シャフト6が外側に拡張し、マーカー7は拡張した管状シャフト6の表面に埋没する。その後、放熱等によって管状シャフト6の温度が軟化点より下がることによって、管状シャフト6が塑性変形した形状で固まり、図11に示すようにマーカー7が管状シャフト6に固定される。

【0030】〔第3実施例〕第3実施例は図面を参照せずに説明する。なお、文中で示す符号は上記実施例で示した符号と同一機能物を示す。上記の第1、第2実施例では、管状シャフト6に加圧や減圧によって拡張力を与えて管状シャフト6の表面にマーカー7を埋没させた例を示したが、この第3実施例では熱を加えることによって、熱が加えられた部分の管状シャフト6が膨らむように設けておき、その管状シャフト6の膨らみによって管状シャフト6の表面にマーカー7を埋没させるものである。

【0031】その概略は、まず管状シャフト6に架橋した樹脂を用い、その架橋された樹脂よりなる管状シャフト6を延伸し、管状シャフト6の外径をマーカー7の内径寸法以下に小径化させる（管状シャフト延伸工程）。次に、この管状シャフト延伸工程で小径化された管状シャフト6にマーカー7を装着し、このマーカー7の装着部位6Aにおける管状シャフト6、あるいはマーカー7の装着部位6Aとその周辺部位の管状シャフト6を形状復帰温度に昇温させる（昇温工程）。

【0032】具体的な製造方法の一例を説明する。直線状低密度ポリエチレン材（溶点125℃）を管状シャフト6に用いる場合、まず、押し出し成形機で外径0.8mm、内径0.5mmに押し出し成形し、このチューブを網状分子構造となるように電子線照射により架橋して強度を上げる。次に、このチューブに外径0.46mmのステンレス鋼線Sを挿入し、80℃に加熱した内径0.56mmのダイスDに通し、5mm/秒の速度で延

伸加工を施す。これによって、外径0.56mm、内径0.46mm、肉厚0.5mmの管状シャフト6が製作される。

【0033】次に、白金90%、イリジウム10%の合金よりなり、外径0.66mm、内径0.56mm、肉厚0.5mm、長さ1mmのマーカー7を、管状シャフト6の所定部位（マーカー設置部位）に装着する。次に、マーカー7の装着部位6Aにおける管状シャフト6およびその周辺部位の管状シャフト6を加熱手段8によって110℃で1分間加熱する。すると、昇温された部分の管状シャフト6がダイス挿通前の形状に復帰するために拡張する。この結果、昇温された部分の管状シャフト6は、管径が過膨張するのを防ぐ加工治具内で拡張し、マーカー7は拡張した管状シャフト6の表面に埋没して固定される。

【0034】〔第4実施例〕第4実施例を図12(a)～(e)を用いて説明する。上記の第1～第3実施例では、筒状に形成したマーカー7を用いた例を示したが、この第4実施例では巻線コイルよりなるマーカー7を用いたものであり、図12(a)は断面が円形の線材7Aを巻回したものであり、図12(b)は断面が矩形の線材7Aを巻回したものであり、図12(c)は断面が楕円形の線材7Aを巻回したものであり、図12(d)は断面が三角の線材7Aを巻回したものであり、図12(e)は断面が台形の線材7Aを巻回したものである。なお、巻線コイルによるマーカー7は、X線不透過のために、上記各実施例で示したようなX線不透過金属を用いるとともに、巻線後の筒状部の厚みは0.5mmに設けられている。

【0035】断面が三角の巻線コイルは、三角の線材7Aの頂部（角）が内側に向けられて巻回されたものであり、また、断面が台形の巻線コイルは、短辺が内側に向けられて巻回されたものである。このような巻線コイルよりなるマーカー7は、第1～第3実施例で示した製造方法によって、管状シャフト6に固定される。なお、巻線コイルとして、断面が円形、楕円形、三角形、台形の線材7Aを用いたことにより、第1～第3実施例で示した製造方法によって、管状シャフト6にマーカー7を固定すると、マーカー7の装着部位6Aにおける管状シャフト6の外周面の拡張によって、管状シャフト6の外側面が巻線コイルの線材7Aと線材7Aとの間の谷部に進入する。

【0036】このように、マーカー7の装着部位6Aにおいて、管状シャフト6の外周面が巻線コイルの線材7Aと線材7Aとの間の谷部に食い込むため、管状シャフト6とマーカー7とが強固に固着される。また、マーカー7を巻線コイルによって設けたことにより、管状シャフト6曲折時にマーカー7が装着された部位においてマーカー7および管状シャフト6の曲折が可能になり、管状シャフト6の応動性が高まる。

【0037】〔第5実施例〕第5実施例を図13(a)～(c)を用いて説明する。この第5実施例は、例えば白金とイリジウムの合金など、X線不透過金属よりなる厚さ0.5mmほどの板状金属を筒状に曲折してマーカー7を作成したもので、筒状に巻回した突き合わせ面7Bは、図13(a)に示すように当接しても良いし、図13(c)に示すようにわずかに離れても良いし、図13(b)に示すように傾斜を持たせて重ね合わせても良い。

#### 10 【図面の簡単な説明】

【図1】マーカーの装着部位の管状シャフト断面図である（第1実施例）。

【図2】端面直角なマーカーを用いた管状シャフト拡張前と拡張後の説明図である（第1実施例）。

【図3】端面が内側に傾斜したマーカーを用いた管状シャフト拡張前と拡張後の説明図である（第1実施例）。

【図4】端面が内側に傾斜したマーカーの要部断面図である（第1実施例）。

【図5】管状シャフト製造の説明図である（第1実施例）。

【図6】マーカー固定の説明図である（第1実施例）。

【図7】マーカーが固定された部分の管状シャフトを示す図である（第1実施例）。

【図8】バルーンカテーテルを用いた治療器具の概略図である（第1実施例）。

【図9】バルーンカテーテルを用いた治療器具の先端側の概略図である（第1実施例）。

【図10】マーカー固定の説明図である（第2実施例）。

【図11】マーカーが固定された部分の管状シャフトを示す断面図である（第2実施例）。

【図12】マーカーに巻線コイルを用いた線材形状を示す図である（第4実施例）。

【図13】マーカーの横断面図である（第5実施例）。

【図14】マーカーの装着部位の管状シャフト断面図である（従来例）。

#### 【符号の説明】

4 バルーンカテーテル

5 外管

5A 拡張バルーン

6 管状シャフト

6A マーカーの装着部位

6B マーカーを挟持する部位

6C マーカーを挟持する部位以外の管状シャフト部位

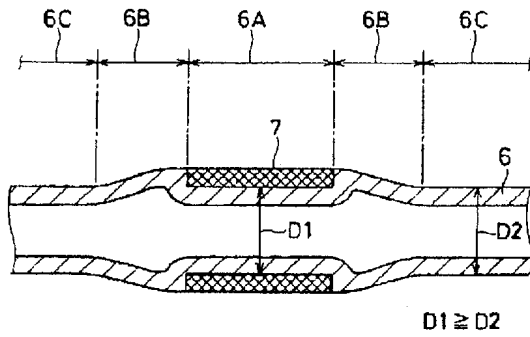
7 マーカー

7A 巻線コイルの線材

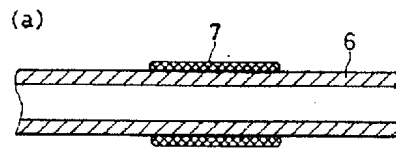
D1 マーカーの装着部位における管状シャフトの外径

D2 マーカーを挟持する部位以外における管状シャフトの外径

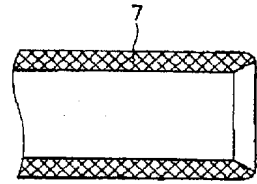
【図1】



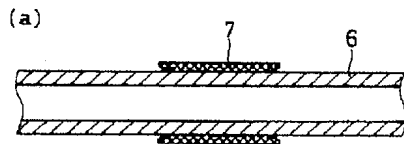
【図2】



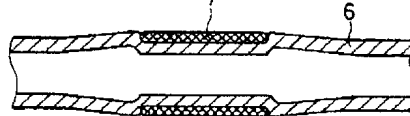
【図4】



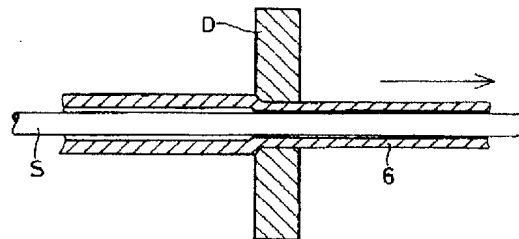
【図3】



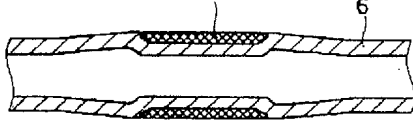
(b)



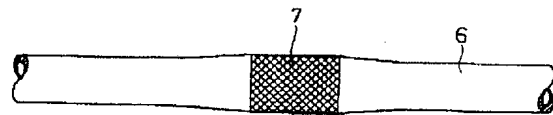
【図5】



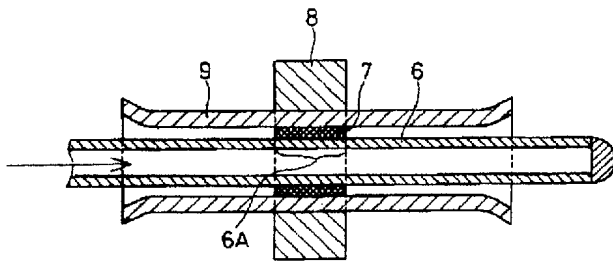
(b)



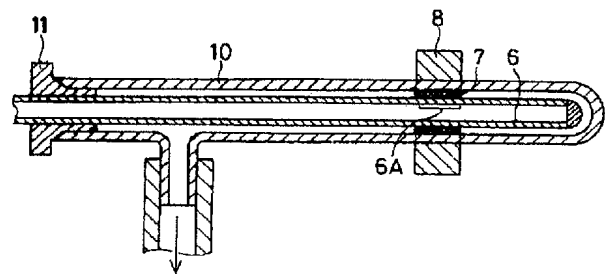
【図7】



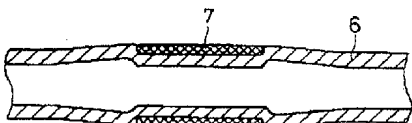
【図6】



【図10】

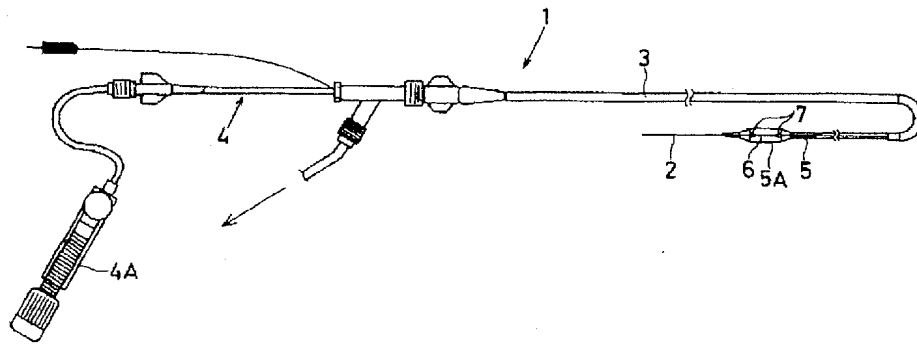


【図11】

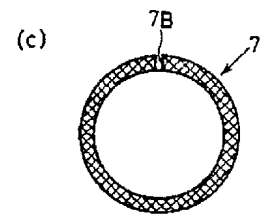
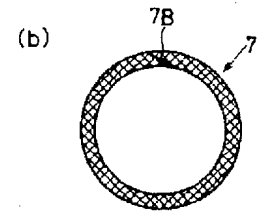
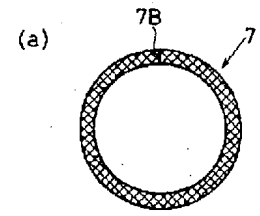




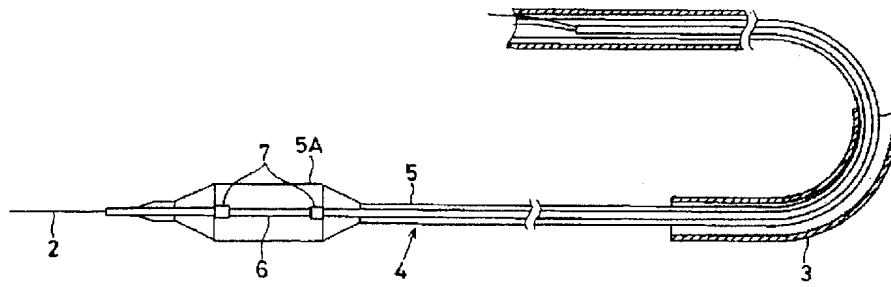
【図 8】



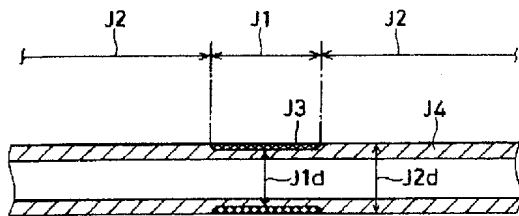
【図 13】



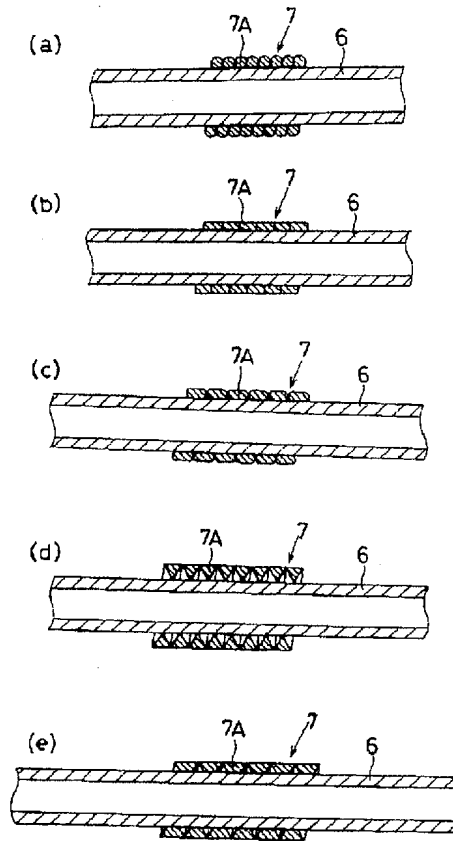
【図 9】



【図 14】



【図12】



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## CLAIMS

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[Claim(s)]

[Claim 1]In a balloon catheter which it has, a radiopacity marker on a peripheral face of a tubular shaft in an inside of an extended balloon said marker, While being inserted into said tubular shaft of both sides of the marker and being fixed to said tubular shaft, an outer diameter of said tubular shaft in mounting parts of said marker, A balloon catheter providing more than an outer diameter of said tubular shafts other than a part which pinches said marker.

[Claim 2]A balloon catheter, wherein said marker consists of a winding coil and a peripheral face of said tubular shaft in mounting parts of said marker advances into a trough between wire rods of said winding coil in a balloon catheter of claim 1.

[Claim 3]A balloon catheter of claim 1 or claim 2, Said tubular shaft [ in / said tubular shaft consists of thermoplastics and / mounting parts of said marker ], Or a manufacturing method of a balloon catheter manufacturing with a temperature rising step which carries out temperature up of said tubular shaft of mounting parts and a circumference part of said marker to temperature of a before [ from softening temperature / a melting point ], a tube diameter extension process of giving extension power to said tubular shaft, and combination of \*\*.

[Claim 4]A balloon catheter of claim 1 or claim 2, A tubular shaft stretching process which extends said tubular shaft which consists of resin in which the bridge was constructed over said tubular shaft, and consists of this resin over which the bridge was constructed, and makes an outer diameter of said tubular shaft byway-ize below to an inner diameter dimension of said marker, Said tubular shaft byway-ized by this tubular shaft stretching process is equipped with said marker, A manufacturing method of a temperature rising step which carries out temperature up of said tubular shaft in mounting parts of this marker, or said tubular shaft of mounting parts and a circumference part of said marker to shape return temperature, and a balloon catheter manufacturing as be alike.

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## DETAILED DESCRIPTION

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[Detailed Description of the Invention]

[0001]

[Field of the Invention]This invention relates to the balloon catheter of medical application. It is related with the fixation of the radiopacity marker fixed especially to a tubular shaft.

[0002]

[Description of the Prior Art]Conventionally, the art indicated by JP,8-289934,A is known as this kind of art. As shown in drawing 14, this art tubular shaft outer diameter J1 d in the mounting parts J1 of the marker J3, Make it smaller than tubular shaft outer diameter J2 d of other parts J2, and the marker J3 is inserted in the tubular shaft J4, The marker J3 is fixed, or from the marker mounting part of the tubular shaft J4, the tubular marker J3 processes a tip part thinly so that insertion is possible, and the marker J3 is fixed with the contraction tube after inserting the marker J3. As methods other than the above-mentioned invention, adhesives are used for the tubular shaft J4, and the marker J3 is fixed to it.

[0003]

[Problem(s) to be Solved by the Invention]However, in order to insert the marker J3 in the tubular shaft J4 in the art shown in the above-mentioned gazette, Since tubular shaft outer diameter J1 d in the mounting parts J1 of the marker J3 is made smaller than tubular shaft outer diameter J2 d of other parts J2, The thickness of the tubular shaft J4 in the mounting parts J1 of the marker J3 will become thin, and a possibility that the tubular shaft J4 will be damaged in the mounting parts J1 (especially near the corner of the marker J3) of the marker J3 will become high. A marker bridging layer is made as for being based on adhesives fixing the marker J3 to the tubular shaft J4 according to a contraction tube to a marker part, if the worst happens, it requires a member for the flexibility of this part to marker attachment simultaneously, and its workability is also bad.

[0004]

[Objects of the Invention]In light of the above-mentioned circumstances, this invention the purpose, In the mounting part of a marker, while losing the level difference of a marker end and the mounting part of a tubular shaft, To immobilization of a marker by narrow diameter-ization of the tip part for formation of the slot for marker immobilization, or tubular marker insertion. It is in offer of the good balloon catheter of flexibility by fixing a marker to a tubular shaft without preventing breakage of the tubular shaft by the thickness of a tubular shaft becoming thin or needing use of a contraction tube, or use of adhesives for a marker bridging again. It is in offer of the balloon catheter which can prevent the thickness of the tubular shaft in the mounting parts of a marker becoming thin, and can prevent breakage of a tubular shaft.

[0005]

[Means for Solving the Problem][A means of claim 1] In a balloon catheter which it has, a radiopacity marker on a peripheral face of a tubular shaft in an inside of an extended balloon said marker, While being inserted into said tubular shaft of both sides of the marker and being fixed to said tubular shaft, an outer diameter of said tubular shaft in mounting parts of said marker was provided more than an outer diameter of said tubular shafts other than a part which pinches said marker.

[0006][A means of claim 2] In a balloon catheter of claim 1, said marker consists of a winding coil and a peripheral face of said tubular shaft in mounting parts of said marker advances into a trough between wire rods of said winding coil.

[0007][A means of claim 3] A balloon catheter of claim 1 or claim 2, Said tubular shaft [ in / said tubular shaft consists of thermoplastics and / mounting parts of said marker ], Or it is manufactured with a temperature rising step which carries out temperature up of said tubular shaft of mounting parts and a circumference part of said marker to temperature of a before [ from softening temperature / a melting point ], a tube diameter extension process of giving extension power to said tubular shaft, and combination of \*\*.

[0008][A means of claim 4] A balloon catheter of claim 1 or claim 2, A tubular shaft stretching process which extends said tubular shaft which consists of resin in which the bridge was constructed over said tubular shaft, and consists of this resin over which the bridge was constructed, and makes an outer diameter of said tubular shaft byway-ize below to an inner diameter dimension of said marker, Said tubular shaft byway-ized by this tubular shaft stretching process is equipped with said marker, Look like [ a temperature rising step which carries out temperature up to shape return temperature ] said tubular shaft in mounting parts of this marker or said tubular shaft of mounting parts and a circumference part of said marker is manufactured.

[0009]

[Function and Effect of the Invention][An operation and effect of claim 1] by having provided

greatly the outer diameter of the tubular shaft in the mounting parts of a marker as compared with the Prior art, the thickness of the tubular shaft in the mounting parts of a marker is thick as compared with a Prior art, and breakage of the tubular shaft in the mounting parts of a marker can be prevented as a result. Since it is inserted into the tubular shaft of the both sides of the marker and is fixed to a tubular shaft, a marker becomes the structure where a tubular shaft exists in the both-sides end of a marker. For this reason, contact with the lateral-angle-of-scapula part of a marker and an extended balloon is suppressed by the pinching part of the tubular shaft which pinches a marker, and breakage of an extended balloon can be prevented as a result.

[0010][An operation and effect of claim 2] By having established the marker with the winding coil, winding of a marker and a tubular shaft is attained in the part to which it was equipped with the marker at the time of tubular shaft winding, and the corresponding movement nature of a tubular shaft increases. And since the peripheral face of the tubular shaft in the mounting parts of a marker is advancing into the trough between the wire rods of a winding coil, a tubular shaft and a marker adhere firmly (since in other words the peripheral face of the tubular shaft is eating away between the wire rods of a winding coil).

[0011][An operation and effect of claim 3] While heating the tubular shaft of the part equipped with a marker to the temperature between softening temperature - a melting point by a temperature rising step, using thermoplastics as a tubular shaft, the tubular shaft of the part where it was heated and heat was transmitted swells by giving extension power to a tubular shaft at a tube diameter extension process. That is, the tubular shaft of the inside of a marker and the both-ends portion of a marker swells, and a marker becomes more than the outer diameter of tubular shafts other than the part where the outer diameter of the tubular shaft in the mounting parts of a marker pinches a marker while being inserted into the tubular shaft of the both sides of the marker. Thus, the balloon catheter of claim 1 or claim 2 can be manufactured.

[0012][An operation and effect of claim 4] A tubular shaft is extended and the outer diameter of a tubular shaft is made to byway-ize below to the inner diameter dimension of a marker according to a tubular shaft stretching process using the resin over which the bridge was constructed as a tubular shaft. Next, it is made to return to the shape before extending the tubular shaft of the part which carried out temperature up of the tubular shaft of the part equipped with a marker, and carried out temperature up by the temperature rising step. That is, the tubular shaft of the inside of a marker and the both-ends portion of a marker swells, and a marker becomes more than the outer diameter of tubular shafts other than the part where the outer diameter of the tubular shaft in the mounting parts of a marker pinches a marker while being inserted into the tubular shaft of the both sides of the marker. Thus, the balloon catheter of claim 1 or claim 2 can be manufactured.

[0013]

[Embodiment of the Invention]An embodiment of the invention is described using two or more examples.

[The 1st example] Drawing 1 - drawing 9 show the 1st example, and explain the treating instrument using a balloon catheter using drawing 8 and drawing 9 first. This treating instrument 1 is what is used for the blood vessel tip side blood-flow inspection, the extended therapy of an intravascular narrow segment, intravascular blood-flow regulation, etc., The guidewire 2 first inserted into a blood vessel for the purpose of a therapy or guidance to an inspection point, It consists of the guide catheter 3 which makes meet this guidewire 2 and is inserted into a blood vessel, and the balloon catheter 4 guided along with the guidewire 2 to a therapy or an inspection point while being inserted into this guide catheter 3 and showing around to near a therapy or the inspection point.

[0014]It consists of the outer tube 5 which this balloon catheter 4 equipped with the extended balloon 5A for affected part extension, and the tubular shaft 6 by which the guidewire 2 is inserted in an inside while being arranged inside this outer tube 5, and the outer tube 5 and the tubular shaft 6 are being fixed in same axle so that it may not shift to the longitudinal direction of a pipe. Operation of extension and contraction is performed by the yne deflator 4A in which the extended balloon 5A was formed in the hand side of the balloon catheter 4. the radiopacity marker 7 for checking the position of the extended balloon 5A through X-rays around the tubular shaft 6 in the inside of the extended balloon 5A -- one -- or more than one have adhered. Drawing 9 shows the example in which the circumference of the tubular shaft 6 in the inside of the extended balloon 5A was equipped with the two markers 7.

[0015]Polyethylene, polypropylene, polyolefine, polyvinyl chloride, a polyamide elastomer, polyurethane, etc. are used for the tubular shaft 6 shown in this example as an example of thermoplastics using thermoplastics. The outer tube 5 shown in this example as well as the tubular shaft 6 uses polyethylene, polypropylene, polyolefine, polyvinyl chloride, a polyamide elastomer, polyurethane, etc. as an example of thermoplastics using thermoplastics.

[0016]Platinum, gold, tungsten, these alloys, platinum, the alloy of iridium, silver, the alloy of palladium, etc. are used for the marker 7 shown in this example as an example of radiopacity metal using the barrels of radiopacity metal. Although the thinner one of the thickness of the marker 7 is desirable from the implications which make a level difference small, from the implications which un-penetrate X-rays and use them for the localization, the thicker one is desirable and is established in a thickness of not less than at least 100 micrometers.

[0017]This marker 7 is embedded at the tubular shaft 6 of the marker 7 circumference, as shown in drawing 1, While the level difference of the surface of the marker 7 and the tubular shaft 6 has lost, being inserted into the tubular shaft 6 of the both sides of the marker 7 and being fixed to the tubular shaft 6, The outer diameter D1 of the tubular shaft 6 in the mounting



parts 6A of the marker 7 is formed more than [ of tubular shaft parts 6C other than pinching part 6B which pinches the marker 7 ] outer diameter D2. The pinching part 6B of the tubular shaft 6 which sandwiches the marker 7 from both sides in the both sides of the marker 7 is formed of the plastic deformation of the tubular shaft 6, and explains an example of the manufacturing method using drawing 2 - drawing 7.

[0018]First, as shown in drawing 2 (a), the marker 7 shown in the predetermined region (marker installation site) of the tubular shaft 6 which consists of thermoplastics shown above above is arranged. Next, temperature up of the tubular shaft 6 in the mounting parts 6A of the marker 7 is carried out to the temperature of a before [ from softening temperature / a melting point ] by the heating method 8 (refer to drawing 6) arranged on the outside of the marker 7 (temperature rising step). While tubular shaft 6 temperature of the mounting parts 6A of the marker 7 carries out temperature up to the temperature of a before [ from the softening temperature of the tubular shaft 6 / a melting point ] according to this temperature rising step, temperature up also of the surrounding tubular shaft 6 of the marker 7 is carried out to the temperature of a before [ from softening temperature / a melting point ] by transfer of heat.

[0019]Next, extension power is given to the tubular shaft 6 of the part where it was equipped with the marker 7 at least by the tubular shaft expansion means (tube diameter extension process). As the tubular shaft 6 of the portion softened by the heating method 8 is extended outside by this tube diameter extension process and it was shown in drawing 1 as a result, while the marker 7 is inserted into the tubular shaft 6 of both sides, Outer diameter D2 of tubular shaft parts 6C other than part 6B in which the outer diameter D1 of the tubular shaft 6 in the mounting parts 6A of the marker 7 pinches the marker 7 It becomes above. Then, when the temperature of the tubular shaft 6 in which temperature up was carried out by forced cooling by a cooling method and natural air cooling by heat dissipation falls from softening temperature, it solidifies in the shape in which the tubular shaft 6 carried out plastic deformation, and the marker 7 is firmly fixed to the predetermined region of the tubular shaft 6.

[0020]Above, after starting a temperature rising step, the example which started the tube diameter extension process was shown, but after starting a tube diameter extension process conversely, a temperature rising step may be started, and a temperature rising step and a tube diameter extension process may be started simultaneously. Although the ring shape heating method which generates heat by energization etc. as an example of the heating method 8 was shown in the example, temperature up may be carried out by other means, such as a hot wind heating method which gives a hot wind.

[0021]Although the length of outer diameter length and the length of inside diameter length were equal and the end face showed the right-angled marker 7 to the example to the tube length as an example of the marker 7 by drawing 2, While shortening inside diameter length and making the end face of the marker 7 incline inside from the length of outer diameter length

as shown in drawing 3 and drawing 4, an outside end surface may be cut off the corners for a circle etc. Thus, while making the end face of the marker 7 incline inside, losing the level difference of the end face of the marker 7 and the surface of the tubular shaft 6 can carry out easily by cutting off the corners to an outside end surface.

[0022]On the other hand, when using crystal polymer materials, such as nylon, polyamide, and polyester, as a material of the tubular shaft 6, the mounting area of the marker 7 at least is good to perform crystal orientation by extension at the time of shaping of the tubular shaft 6, and to raise intensity. By this, even if the tubular shaft 6 extends and changes by temperature up and extension, the strength reduction of the modification part of the tubular shaft 6 can be prevented. When linear macromolecule materials, such as polyethylene, are used as a material of the tubular shaft 6, . [ whether intensity is raised as network structure according to heating bridge construction by adding the cross linking agent at the time of shaping of the tubular shaft 6, and ] After making intramolecular generate a radical by electron beam radiation, and making it strengthen after shaping of the tubular shaft 6 or equipping the tubular shaft 6 with the marker 7, it is good to perform heat-treatment and electron-beam-irradiation processing, and to raise intensity. Even if it bends, and it crushes to the mounting area of the marker 7 and loads, such as torsion, are added to it by this, there is no fault which the tubular shaft 6 of the mounting area of the marker 7 damages.

[0023]The example of a more concrete manufacturing method is described using drawing 5 - drawing 7. Temporary extrusion formation of Nylon 12 which is thermoplastic polyamide system resin is carried out first at tube shape the outer diameter of 0.75 mm, and 0.5 mm in inside diameter. Next, as shown in drawing 5, with an outer diameter of 0.46 mm stainless steel wire S is inserted in this tube, and through and a stretching process are performed to the dice D 0.56 mm in inside diameter subsequently to 150 \*\* heated. The tubular shaft 6 is manufactured by this. As for the nylon which makes the tubular shaft 6, orientation of the crystal is carried out by the stretching process. Under the present circumstances, annealing treatment is performed for the stress relieving by extension of the tubular shaft 6. In this example, the with the outer diameter of 0.56 mm, 0.46 mm in inside diameter, and a thickness of 0.5 mm tubular shaft 6 was manufactured.

[0024]Next, the tubed marker 7 which becomes a predetermined region (marker installation site) of the tubular shaft 6 from radiopacity metal is arranged. The marker 7 in this case could be inserted in the tubular shaft 6, and a thing the outer diameter of 0.66 mm, 0.56 mm in inside diameter, the thickness of 0.5 mm, and 1 mm in length was used for it. Next, extension power is given to the tubular shaft 6 of the part where it was equipped with the marker 7 at least. The tubular shaft expansion means in this example pressurizes the inside of the tubular shaft 6, as shown in drawing 6, and the end of the tubular shaft 6 is beforehand blockaded with heat sealing, adhesives, etc. And the booster pump which is not illustrated is connected to the other

end of the tubular shaft 6, and the inside of the tubular shaft 6 is pressurized with air (tube diameter extension process).

[0025]Next, temperature up of the tubular shaft 6 in the mounting parts 6A of the marker 7 is carried out to the temperature of a before [ from softening temperature / a melting point ] by the heating method 8 (annular heating heater) arranged on the outside of the marker 7 (temperature rising step). The tubular shaft 6 of the portion which it was heated and was softened according to the tube diameter extension process and the temperature rising step is extended outside, and the marker 7 is buried in the surface of the extended tubular shaft 6. Then, when the temperature of the tubular shaft 6 falls from softening temperature by heat dissipation etc., it solidifies in the shape in which the tubular shaft 6 carried out plastic deformation, and the marker 7 is fixed to the tubular shaft 6 as shown in drawing 7.

[0026]In order to prevent the hyperdiastole of the tubular shaft 6 since a level difference arises on the surface of the connection section of the marker 7 and the tubular shaft 6 if extension of the tubular shaft 6 exceeds the outer diameter of the marker 7, In this example, the tube diameter working jig 9 has been arranged around the tubular shaft 6 and the marker 7, and the tube diameter extension process and the temperature rising step were carried out. This tube diameter working jig 9 consists of heat resisting glass tubes, for example, and the inside diameter is provided almost similarly to the outer diameter of the marker 7. By using this tube diameter working jig 9, the hyperdiastole of the tubular shaft 6 is prevented and the fault which a level difference produces on the surface of the connection section of the marker 7 and the tubular shaft 6 can be prevented certainly.

[0027][Effect of Example(s)]Outer diameter D2 of a tubular shaft [ outer diameter / D1 / of the tubular shaft 6 in the mounting parts 6A of the marker 7 ] part 6C other than pinching part 6B of the marker 7 It is provided above. That is, the outer diameter D1 of the tubular shaft 6 in the mounting parts 6A of the marker 7 is large as compared with a Prior art. By this, thickness of the tubular shaft 6 in the mounting parts 6A of the marker 7 is thickly made as compared with a Prior art, and breakage of the tubular shaft 6 in the mounting parts 6A of the marker 7 can be prevented as a result. It was inserted into the tubular shaft 6 of the both sides of the marker 7, and was fixed to the tubular shaft 6, and the level difference of the surface of the marker 7 and the tubular shaft 6 has abolished the marker 7. On the other hand, since there is no necessity for the immobilization by a contraction tube or immobilization by adhesives in immobilization in the tubular shaft 6 of the marker 7 from the outside of the marker 7, There is no resistance to the crookedness by bridgings, such as this of a marker part, and there is also no level difference of the end of the marker 7 and the mounting part of the tubular shaft 6, and the marker part was able to be created smoothly.

[0028][The 2nd example] The 2nd example is described using drawing 10 and drawing 11. In the 1st above-mentioned example, when the marker 7 was fixed to the tubular shaft 6, a

means to have pressurized the inside of the tubular shaft 6 and to extend the tubular shaft 6 was shown, but this 2nd example shows a means to decompress the exterior of the tubular shaft 6 and to extend the tubular shaft 6. The tubular shaft 6 blockades the end with heat sealing or adhesives beforehand like the 1st example. And the tubed marker 7 which becomes a predetermined region (marker installation site) of the tubular shaft 6 from radiopacity metal is arranged. This is inserted in the inside of the heat-resistant glass heating fixture 10 for decompression processing. This heat-resistant glass heating fixture 10 is a tube which consists of heat-resistant glass, and that inside diameter is provided in the size which was mostly in agreement with the outer diameter of the marker 7, in order to prevent the overexpansion of the tubular shaft 6.

[0029]In a tube diameter extension process, where between the heat-resistant glass heating fixtures 10 and the tubular shafts 6 in the end (open end which inserts the tubular shaft 6) of the heat-resistant glass heating fixture 10 is blockaded with the rubber seal plug 11, the inside of the heat-resistant glass heating fixture 10 is decompressed with the decompression pump which is not illustrated. And temperature up of the tubular shaft 6 in the mounting parts 6A of the marker 7 is carried out to the temperature of a before [ from softening temperature / a melting point ] by the heating method 8 (annular heating heater) arranged on the outside of the marker 7. The tubular shaft 6 of the portion which it was heated and was softened like the 1st example by this is extended outside, and the marker 7 is buried in the surface of the extended tubular shaft 6. Then, when the temperature of the tubular shaft 6 falls from softening temperature by heat dissipation etc., it solidifies in the shape in which the tubular shaft 6 carried out plastic deformation, and the marker 7 is fixed to the tubular shaft 6 as shown in drawing 11.

[0030][The 3rd example] The 3rd example is described without referring to drawings. The functional [ that the numerals shown in a sentence are the same ] thing as the numerals shown in the above-mentioned example is shown. Although the 1st and 2nd above-mentioned example showed the example which gave extension power to the tubular shaft 6 with application of pressure or decompression, and made the marker 7 buried in the surface of the tubular shaft 6, It provides so that the tubular shaft 6 of the portion to which heat was applied may swell, and the marker 7 is made buried in the surface of the tubular shaft 6 with the swelling of that tubular shaft 6 by applying heat in this 3rd example.

[0031]The outline extends the tubular shaft 6 which consists of the resin over which the bridge was constructed using the resin which constructed the bridge over the tubular shaft 6 first, and makes the outer diameter of the tubular shaft 6 byway-ize below to the inner diameter dimension of the marker 7 (tubular shaft stretching process). Next, the tubular shaft 6 byway-ized by this tubular shaft stretching process is equipped with the marker 7, and temperature up of the tubular shaft 6 in the mounting parts 6A of this marker 7 or the tubular shaft 6 of the

mounting parts 6A and the circumference part of the marker 7 is carried out to shape return temperature (temperature rising step).

[0032]An example of a concrete manufacturing method is explained. When using linear shape low-density-polyethylene material (melting point of 125 \*\*) for the tubular shaft 6, first, extrusion molding is carried out to the outer diameter of 0.8 mm, and 0.5 mm in inside diameter with extruder, a bridge is constructed by electron beam irradiation and intensity is raised so that it may become reticular molecule structure about this tube. Next, with an outer diameter of 0.46 mm stainless steel wire S is inserted in this tube, and a stretching process is performed to the dice D 0.56 mm in inside diameter heated at 80 \*\* at 5 mm/second in through and speed. The with the outer diameter of 0.56 mm, 0.46 mm in inside diameter, and a thickness of 0.5 mm tubular shaft 6 is manufactured by this.

[0033]Next, it consists of 90% of platinum, and iridium 10% of an alloy, and the predetermined region (marker installation site) of the tubular shaft 6 is equipped with the marker 7 the outer diameter of 0.66 mm, 0.56 mm in inside diameter, the thickness of 0.5 mm, and 1 mm in length. Next, the tubular shaft 6 in the mounting parts 6A of the marker 7 and the tubular shaft 6 of the circumference part are heated for 1 minute at 110 \*\* by the heating method 8. Then, in order that the tubular shaft 6 of the portion by which temperature up was carried out may return to the shape before dice insertion, it extends. As a result, it extends within the working jig which prevents a tube diameter carrying out the overexpansion of the tubular shaft 6 of the portion by which temperature up was carried out, and the marker 7 is buried and fixed to the surface of the extended tubular shaft 6.

[0034][The 4th example] The 4th example is described using drawing 12 (a) - (e). Although the above 1st - the 3rd example showed the example using the marker 7 formed in tubed, The marker 7 which consists of a winding coil in this 4th example is used, Drawing 12 (a) winds the wire rod 7A with a circular section, and, as for drawing 12 (b), a section winds the rectangular wire rod 7A, Drawing 12 (c) winds the wire rod 7A of an ellipse form [ section ], a section winds the triangular wire rod 7A, and, as for drawing 12 (d), drawing 12 (e) winds the wire rod 7A of a trapezoid [ section ]. While radiopacity metal as shown in each above-mentioned example for radiopacity is used for the marker 7 with a winding coil, the thickness of the tubed part after winding is provided in 0.5 mm.

[0035]As for a triangular winding coil, the crowning (angle) of the triangular wire rod 7A is turned inside, a section is wound around it, and a shorter side is turned inside and the winding coil of a trapezoid [ section ] is wound. The marker 7 which consists of such a winding coil is fixed to the tubular shaft 6 by the manufacturing method shown in the 1st - the 3rd example. When the section used circular, the ellipse form, the triangle, and the trapezoid wire rod 7A as a winding coil, If the marker 7 is fixed to the tubular shaft 6 with the manufacturing method shown in the 1st - the 3rd example, the lateral surface of the tubular shaft 6 will advance into

the trough between the wire rod 7A of a winding coil, and the wire rod 7A by extension of the peripheral face of the tubular shaft 6 in the mounting parts 6A of the marker 7.

[0036]Thus, in the mounting parts 6A of the marker 7, since the peripheral face of the tubular shaft 6 eats into the trough between the wire rod 7A of a winding coil, and the wire rod 7A, the tubular shaft 6 and the marker 7 adhere firmly. By having established the marker 7 with the winding coil, in the part to which it was equipped with the marker 7 at the time of tubular shaft 6 winding, winding of the marker 7 and the tubular shaft 6 is attained, and the corresponding movement nature of the tubular shaft 6 increases.

[0037][The 5th example] The 5th example is described using drawing 13 (a) - (c). This 5th example is what platinum, the alloy of iridium, etc. bent in tubed tabular metal with a thickness of about 0.5 mm which consists of radiopacity metal, for example, and created the marker 7, The abutting surface 7B wound around tubed may contact, as shown in drawing 13 (a), as shown in drawing 13 (c), it may be left slightly, and as shown in drawing 13 (b), it may give and pile up an inclination.

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TECHNICAL FIELD

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[Field of the Invention]This invention relates to the balloon catheter of medical application.  
It is related with the fixation of the radiopacity marker fixed especially to a tubular shaft.

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PRIOR ART

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[Description of the Prior Art]Conventionally, the art indicated by JP,8-289934,A is known as this kind of art. As shown in drawing 14, this art tubular shaft outer diameter J1 d in the mounting parts J1 of the marker J3, Make it smaller than tubular shaft outer diameter J2 d of other parts J2, and the marker J3 is inserted in the tubular shaft J4, The marker J3 is fixed, or from the marker mounting part of the tubular shaft J4, the tubular marker J3 processes a tip part thinly so that insertion is possible, and the marker J3 is fixed with the contraction tube after inserting the marker J3. As methods other than the above-mentioned invention, adhesives are used for the tubular shaft J4, and the marker J3 is fixed to it.

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**EFFECT OF THE INVENTION**

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[Function and Effect of the Invention][An operation and effect of claim 1] by having provided greatly the outer diameter of the tubular shaft in the mounting parts of a marker as compared with the Prior art, the thickness of the tubular shaft in the mounting parts of a marker is thick as compared with a Prior art, and breakage of the tubular shaft in the mounting parts of a marker can be prevented as a result. Since it is inserted into the tubular shaft of the both sides of the marker and is fixed to a tubular shaft, a marker becomes the structure where a tubular shaft exists in the both-sides end of a marker. For this reason, contact with the lateral-angle-of-scapula part of a marker and an extended balloon is suppressed by the pinching part of the tubular shaft which pinches a marker, and breakage of an extended balloon can be prevented as a result.

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**TECHNICAL PROBLEM**

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[Problem(s) to be Solved by the Invention]However, in order to insert the marker J3 in the tubular shaft J4 in the art shown in the above-mentioned gazette, Since tubular shaft outer diameter J1 d in the mounting parts J1 of the marker J3 is made smaller than tubular shaft outer diameter J2 d of other parts J2, The thickness of the tubular shaft J4 in the mounting parts J1 of the marker J3 will become thin, and a possibility that the tubular shaft J4 will be damaged in the mounting parts J1 (especially near the corner of the marker J3) of the marker J3 will become high. A marker bridging layer is made as for being based on adhesives fixing the marker J3 to the tubular shaft J4 according to a contraction tube to a marker part, if the worst happens, it requires a member for the flexibility of this part to marker attachment simultaneously, and its workability is also bad.

[0004]

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**MEANS**

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[Means for Solving the Problem]

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## EXAMPLE

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[The 1st example] Drawing 1 - drawing 9 show the 1st example, and explain the treating instrument using a balloon catheter using drawing 8 and drawing 9 first. This treating instrument 1 is what is used for the blood vessel tip side blood-flow inspection, the extended therapy of an intravascular narrow segment, intravascular blood-flow regulation, etc., The guidewire 2 first inserted into a blood vessel for the purpose of a therapy or guidance to an inspection point, It consists of the guide catheter 3 which makes meet this guidewire 2 and is inserted into a blood vessel, and the balloon catheter 4 guided along with the guidewire 2 to a therapy or an inspection point while being inserted into this guide catheter 3 and showing around to near a therapy or the inspection point.

[0014]It consists of the outer tube 5 which this balloon catheter 4 equipped with the extended balloon 5A for affected part extension, and the tubular shaft 6 by which the guidewire 2 is inserted in an inside while being arranged inside this outer tube 5, and the outer tube 5 and the tubular shaft 6 are being fixed in same axle so that it may not shift to the longitudinal direction of a pipe. Operation of extension and contraction is performed by the pneumatic deflator 4A in which the extended balloon 5A was formed in the hand side of the balloon catheter 4. the radiopacity marker 7 for checking the position of the extended balloon 5A through X-rays around the tubular shaft 6 in the inside of the extended balloon 5A -- one -- or more than one have adhered. Drawing 9 shows the example in which the circumference of the tubular shaft 6 in the inside of the extended balloon 5A was equipped with the two markers 7.

[0015]Polyethylene, polypropylene, polyolefine, polyvinyl chloride, a polyamide elastomer, polyurethane, etc. are used for the tubular shaft 6 shown in this example as an example of thermoplastics using thermoplastics. The outer tube 5 shown in this example as well as the tubular shaft 6 uses polyethylene, polypropylene, polyolefine, polyvinyl chloride, a polyamide elastomer, polyurethane, etc. as an example of thermoplastics using thermoplastics.

[0016]Platinum, gold, tungsten, these alloys, platinum, the alloy of iridium, silver, the alloy of

palladium, etc. are used for the marker 7 shown in this example as an example of radiopacity metal using the barrels of radiopacity metal. Although the thinner one of the thickness of the marker 7 is desirable from the implications which make a level difference small, from the implications which un-penetrate X-rays and use them for the localization, the thicker one is desirable and is established in a thickness of not less than at least 100 micrometers.

[0017]As shown in drawing 1, this marker 7 was embedded at the tubular shaft 6 of the marker 7 circumference, and the level difference of the surface of the marker 7 and the tubular shaft 6 has abolished it.

Outer diameter D1 of the tubular shaft 6 in the mounting parts 6A of the marker 7 while being inserted into the tubular shaft 6 of the both sides of the marker 7 and being fixed to the tubular shaft 6. It is provided more than [ of tubular shaft parts 6C other than pinching part 6B which pinches the marker 7 ] outer diameter D2.

The pinching part 6B of the tubular shaft 6 which sandwiches the marker 7 from both sides in the both sides of the marker 7 is formed of the plastic deformation of the tubular shaft 6, and explains an example of the manufacturing method using drawing 2 - drawing 7.

[0018]First, as shown in drawing 2 (a), the marker 7 shown in the predetermined region (marker installation site) of the tubular shaft 6 which consists of thermoplastics shown above above is arranged. Next, temperature up of the tubular shaft 6 in the mounting parts 6A of the marker 7 is carried out to the temperature of a before [ from softening temperature / a melting point ] by the heating method 8 (refer to drawing 6) arranged on the outside of the marker 7 (temperature rising step). While tubular shaft 6 temperature of the mounting parts 6A of the marker 7 carries out temperature up to the temperature of a before [ from the softening temperature of the tubular shaft 6 / a melting point ] according to this temperature rising step, temperature up also of the surrounding tubular shaft 6 of the marker 7 is carried out to the temperature of a before [ from softening temperature / a melting point ] by transfer of heat.

[0019]Next, extension power is given to the tubular shaft 6 of the part where it was equipped with the marker 7 at least by the tubular shaft expansion means (tube diameter extension process). As the tubular shaft 6 of the portion softened by the heating method 8 is extended outside by this tube diameter extension process and it was shown in drawing 1 as a result, while the marker 7 is inserted into the tubular shaft 6 of both sides, Outer diameter D2 of tubular shaft parts 6C other than part 6B in which the outer diameter D1 of the tubular shaft 6 in the mounting parts 6A of the marker 7 pinches the marker 7 It becomes above. Then, when the temperature of the tubular shaft 6 in which temperature up was carried out by forced cooling by a cooling method and natural air cooling by heat dissipation falls from softening temperature, it solidifies in the shape in which the tubular shaft 6 carried out plastic deformation, and the marker 7 is firmly fixed to the predetermined region of the tubular shaft 6.

[0020]Above, after starting a temperature rising step, the example which started the tube

diameter extension process was shown, but after starting a tube diameter extension process conversely, a temperature rising step may be started, and a temperature rising step and a tube diameter extension process may be started simultaneously. Although the ring shape heating method which generates heat by energization etc. as an example of the heating method 8 was shown in the example, temperature up may be carried out by other means, such as a hot wind heating method which gives a hot wind.

[0021]Although the length of outer diameter length and the length of inside diameter length were equal and the end face showed the right-angled marker 7 to the example to the tube length as an example of the marker 7 by drawing 2, While shortening inside diameter length and making the end face of the marker 7 incline inside from the length of outer diameter length as shown in drawing 3 and drawing 4, an outside end surface may be cut off the corners for a circle etc. Thus, while making the end face of the marker 7 incline inside, losing the level difference of the end face of the marker 7 and the surface of the tubular shaft 6 can carry out easily by cutting off the corners to an outside end surface.

[0022]On the other hand, when using crystal polymer materials, such as nylon, polyamide, and polyester, as a material of the tubular shaft 6, the mounting area of the marker 7 at least is good to perform crystal orientation by extension at the time of shaping of the tubular shaft 6, and to raise intensity. By this, even if the tubular shaft 6 extends and changes by temperature up and extension, the strength reduction of the modification part of the tubular shaft 6 can be prevented. When linear macromolecule materials, such as polyethylene, are used as a material of the tubular shaft 6, . [ whether intensity is raised as network structure according to heating bridge construction by adding the cross linking agent at the time of shaping of the tubular shaft 6, and ] After making intramolecular generate a radical by electron beam radiation, and making it strengthen after shaping of the tubular shaft 6 or equipping the tubular shaft 6 with the marker 7, it is good to perform heat-treatment and electron-beam-irradiation processing, and to raise intensity. Even if it bends, and it crushes to the mounting area of the marker 7 and loads, such as torsion, are added to it by this, there is no fault which the tubular shaft 6 of the mounting area of the marker 7 damages.

[0023]The example of a more concrete manufacturing method is described using drawing 5 - drawing 7. Temporary extrusion formation of Nylon 12 which is thermoplastic polyamide system resin is carried out first at tube shape the outer diameter of 0.75 mm, and 0.5 mm in inside diameter. Next, as shown in drawing 5, with an outer diameter of 0.46 mm stainless steel wire S is inserted in this tube, and through and a stretching process are performed to the dice D 0.56 mm in inside diameter subsequently to 150 \*\* heated. The tubular shaft 6 is manufactured by this. As for the nylon which makes the tubular shaft 6, orientation of the crystal is carried out by the stretching process. Under the present circumstances, annealing treatment is performed for the stress relieving by extension of the tubular shaft 6. In this

example, the with the outer diameter of 0.56 mm, 0.46 mm in inside diameter, and a thickness of 0.5 mm tubular shaft 6 was manufactured.

[0024]Next, the tubed marker 7 which becomes a predetermined region (marker installation site) of the tubular shaft 6 from radiopacity metal is arranged. The marker 7 in this case could be inserted in the tubular shaft 6, and a thing an outer diameter of 0.66 mm, 0.56 mm in inside diameter, thickness of 0.5 mm, and 1 mm in length was used for it. Next, extension power is given to the tubular shaft 6 of a part where it was equipped with the marker 7 at least. A tubular shaft expansion means in this example pressurizes an inside of the tubular shaft 6, as shown in drawing 6.

An end of the tubular shaft 6 is beforehand blockaded with heat sealing, adhesives, etc. And a booster pump which is not illustrated is connected to the other end of the tubular shaft 6, and an inside of the tubular shaft 6 is pressurized with air (tube diameter extension process). [0025]Next, temperature up of the tubular shaft 6 in the mounting parts 6A of the marker 7 is carried out to temperature of a before [ from softening temperature / a melting point ] by the heating method 8 (annular heating heater) arranged on the outside of the marker 7 (temperature rising step). The tubular shaft 6 of a portion which it was heated and was softened according to a tube diameter extension process and a temperature rising step is extended outside, and the marker 7 is buried in the surface of the extended tubular shaft 6. Then, when temperature of the tubular shaft 6 falls from softening temperature by heat dissipation etc., it solidifies in shape in which the tubular shaft 6 carried out plastic deformation, and the marker 7 is fixed to the tubular shaft 6 as shown in drawing 7.

[0026]In order to prevent the hyperdiastole of the tubular shaft 6 since a level difference arises on the surface of the connection section of the marker 7 and the tubular shaft 6 if extension of the tubular shaft 6 exceeds the outer diameter of the marker 7, In this example, the tube diameter working jig 9 has been arranged around the tubular shaft 6 and the marker 7, and the tube diameter extension process and the temperature rising step were carried out. This tube diameter working jig 9 consists of heat resisting glass tubes, for example, and the inside diameter is provided almost similarly to the outer diameter of the marker 7. By using this tube diameter working jig 9, the hyperdiastole of the tubular shaft 6 is prevented and the fault which a level difference produces on the surface of the connection section of the marker 7 and the tubular shaft 6 can be prevented certainly.

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[Translation done.]

## \* NOTICES \*

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- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.\*\*\*\* shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

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## DESCRIPTION OF DRAWINGS

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### [Brief Description of the Drawings]

[Drawing 1]It is a tubular shaft sectional view of the mounting parts of a marker (the 1st example).

[Drawing 2]the end face -- it is an explanatory view tubular shaft extension before using a right-angled marker, and after extension (the 1st example).

[Drawing 3]The end face is an explanatory view tubular shaft extension before using the marker inclined inside, and after extension (the 1st example).

[Drawing 4]The end face is an important section sectional view of the marker inclined inside (the 1st example).

[Drawing 5]It is an explanatory view of tubular shaft manufacture (the 1st example).

[Drawing 6]It is an explanatory view of marker immobilization (the 1st example).

[Drawing 7]It is a figure showing the tubular shaft of the portion to which the marker was fixed (the 1st example).

[Drawing 8]It is a schematic diagram of the treating instrument using a balloon catheter (the 1st example).

[Drawing 9]It is a schematic diagram by the side of the tip of the treating instrument using a balloon catheter (the 1st example).

[Drawing 10]It is an explanatory view of marker immobilization (the 2nd example).

[Drawing 11]It is a sectional view showing the tubular shaft of the portion to which the marker was fixed (the 2nd example).

[Drawing 12]It is a figure showing the wire rod shape where the winding coil was used in a marker (the 4th example).

[Drawing 13]It is a cross-sectional view of a marker (the 5th example).

[Drawing 14]It is a tubular shaft sectional view of the mounting parts of a marker (conventional example).



[Description of Notations]

4 Balloon catheter

5 Outer tube

5A Extended balloon

6 Tubular shaft

6A Mounting parts of a marker

6B The part which pinches a marker

6C Tubular shaft parts other than the part which pinches a marker

7 Marker

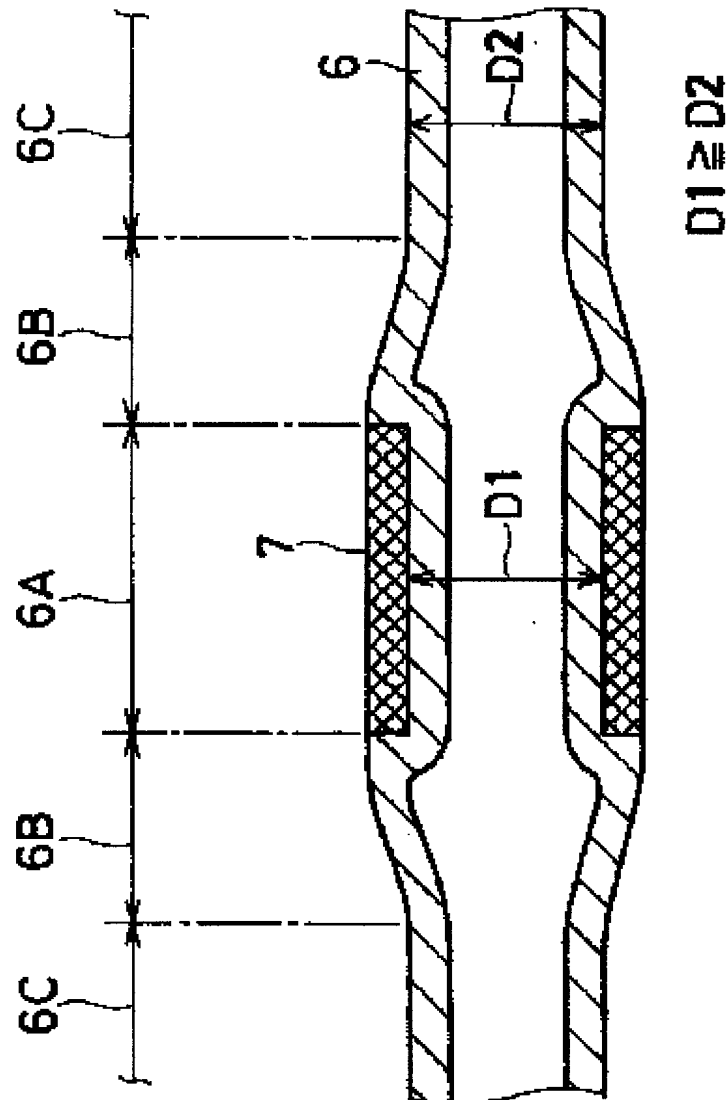
7A The wire rod of a winding coil

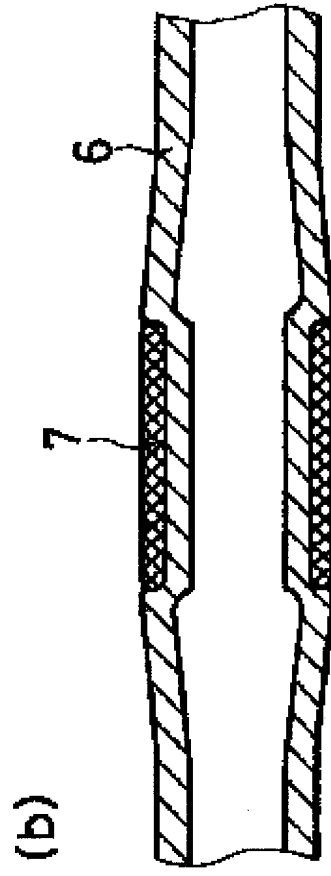
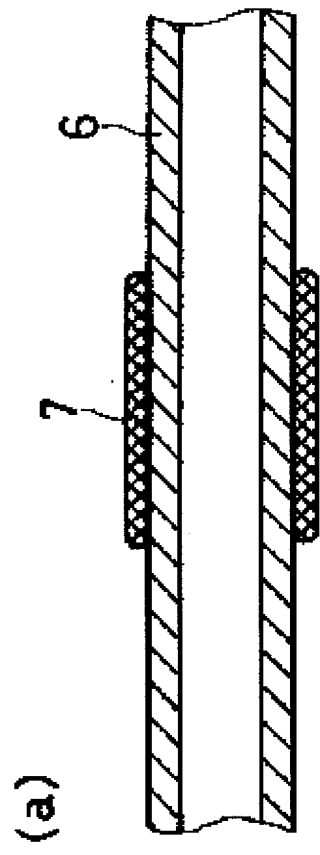
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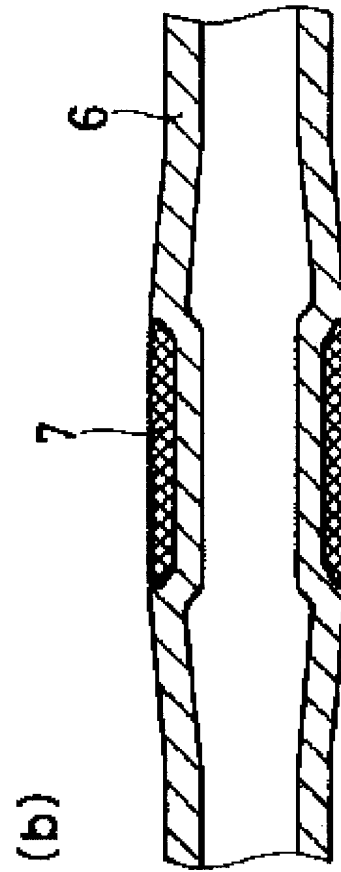
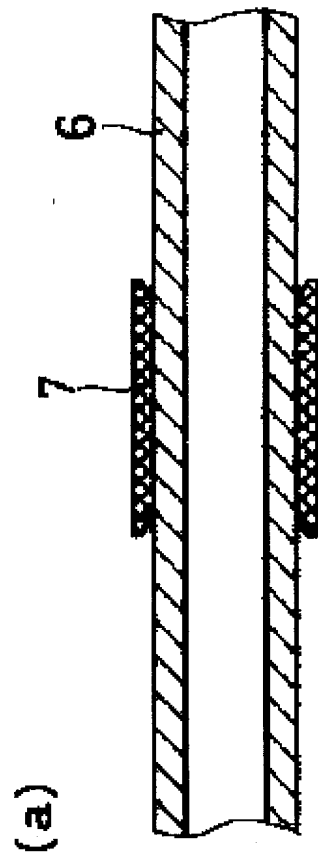
The outer diameter of tubular shafts other than the part which pinches D2 marker

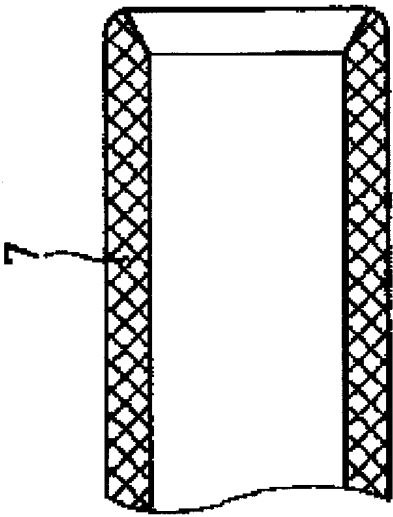
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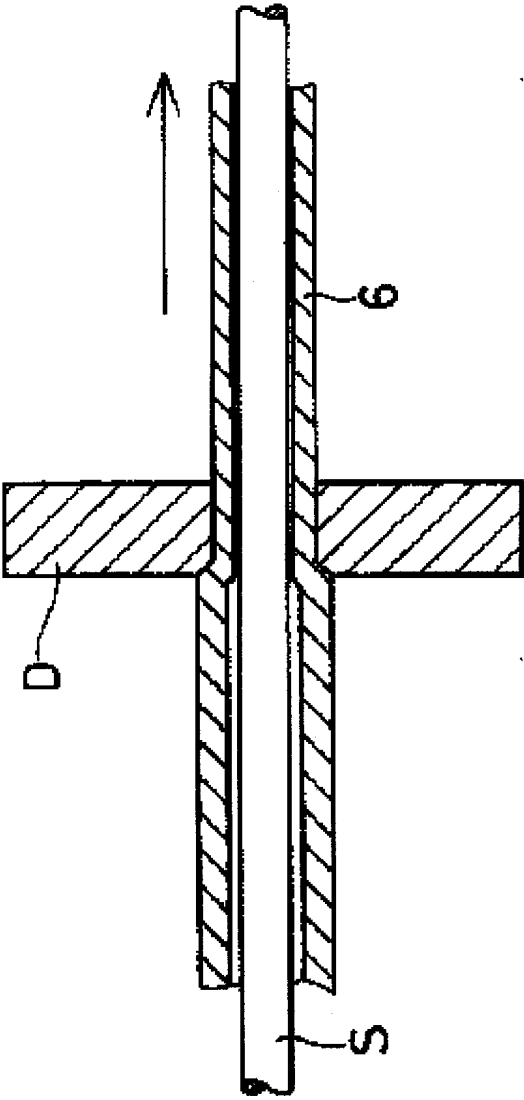
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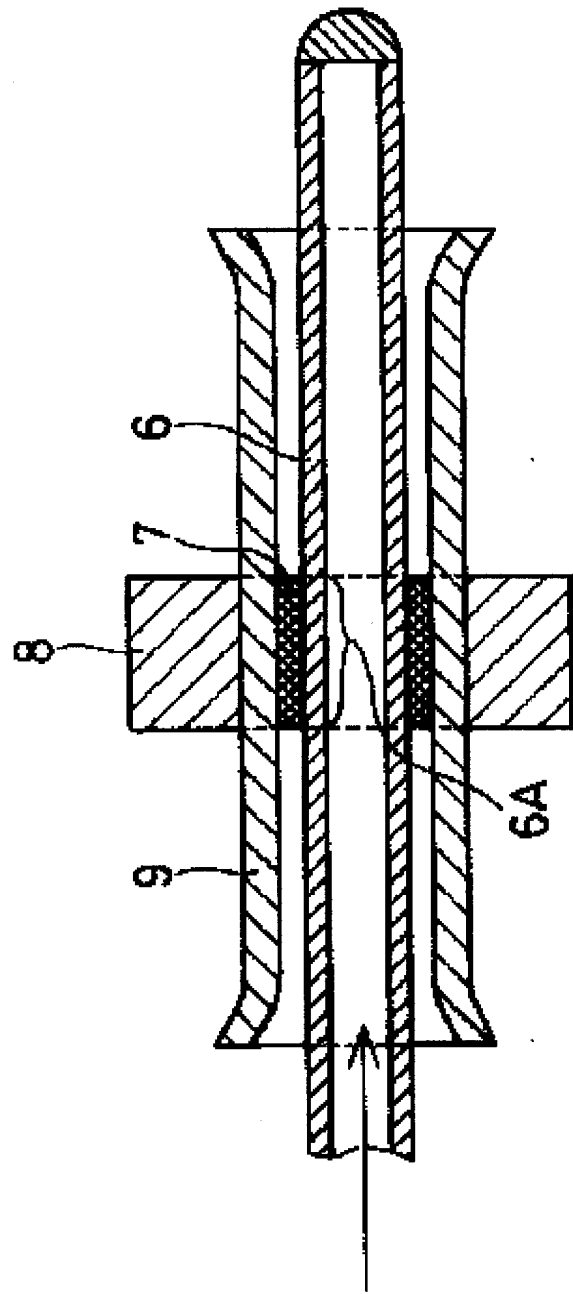




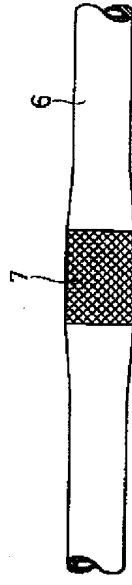






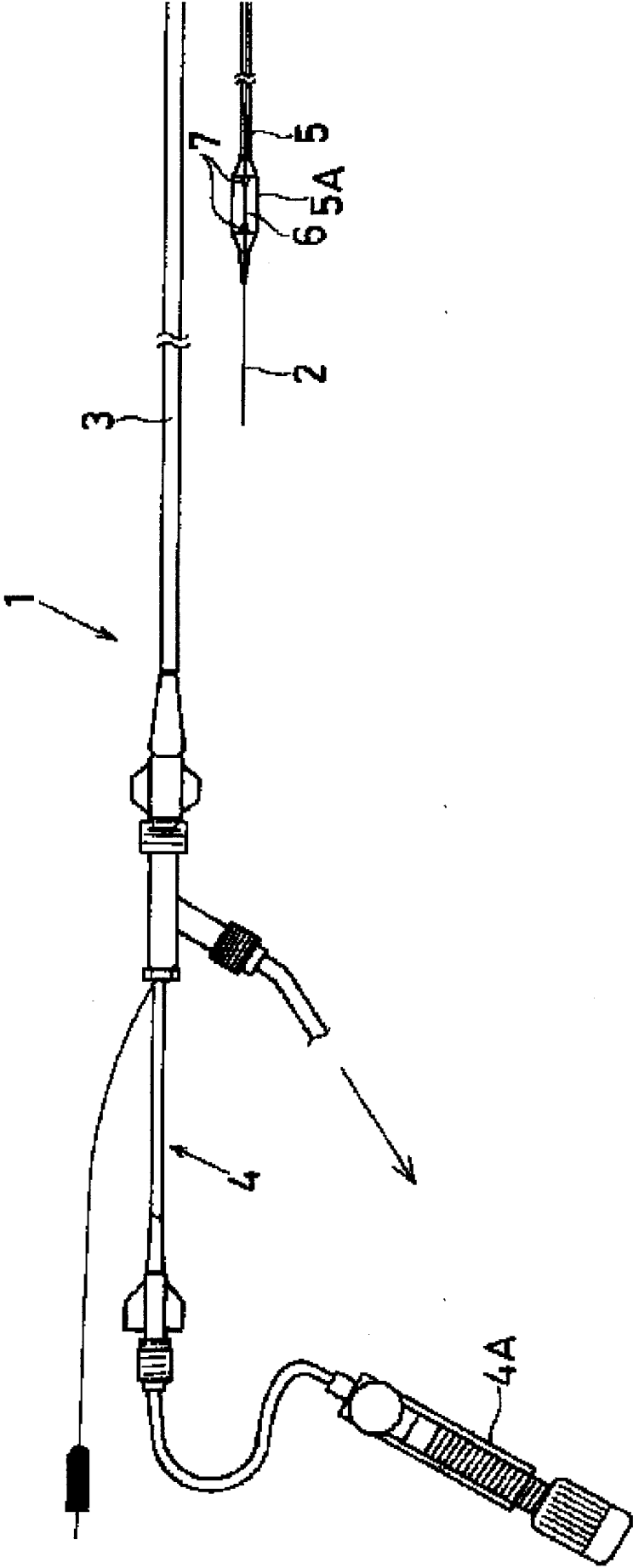


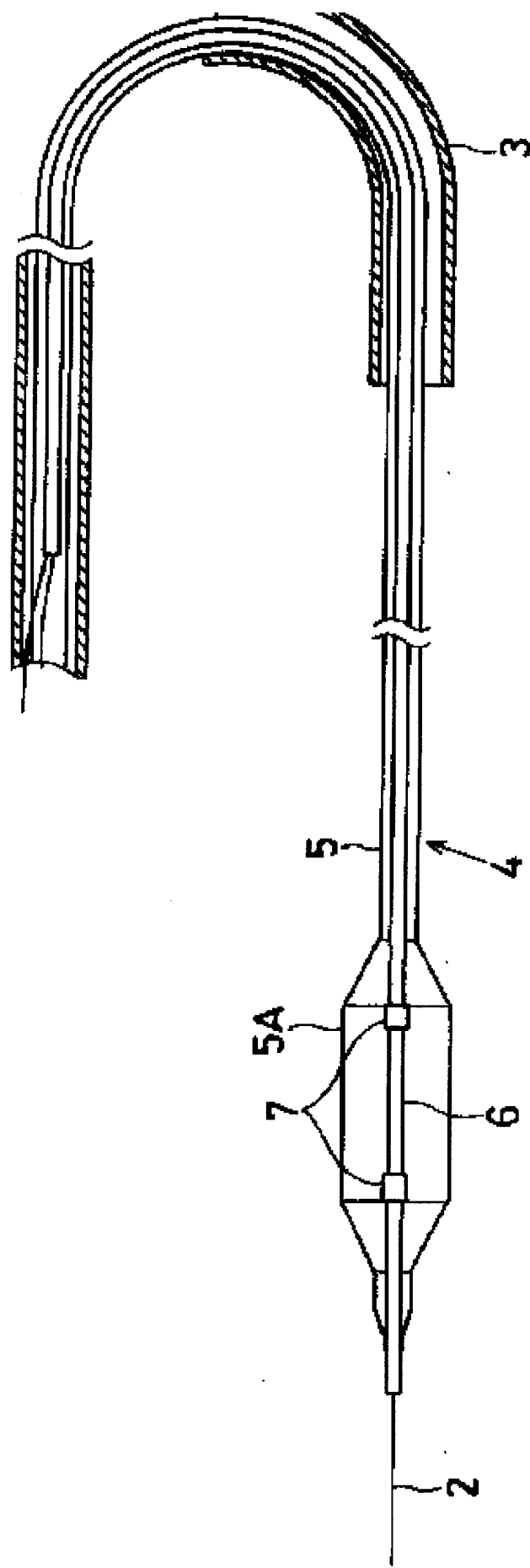
Drawing selection Drawing 7

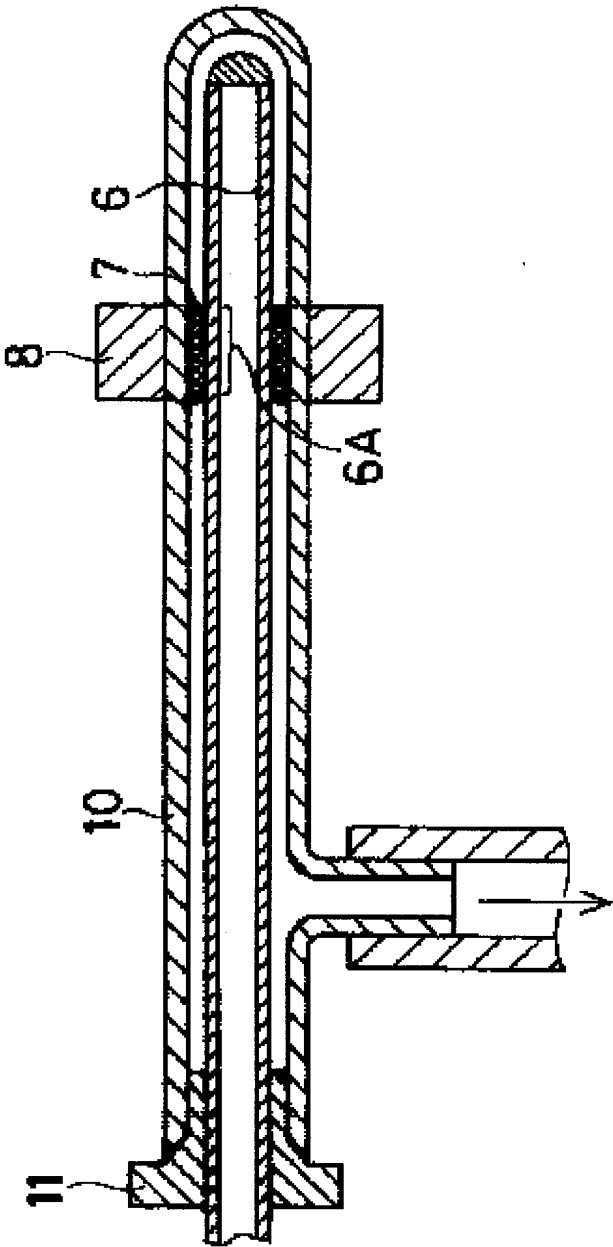


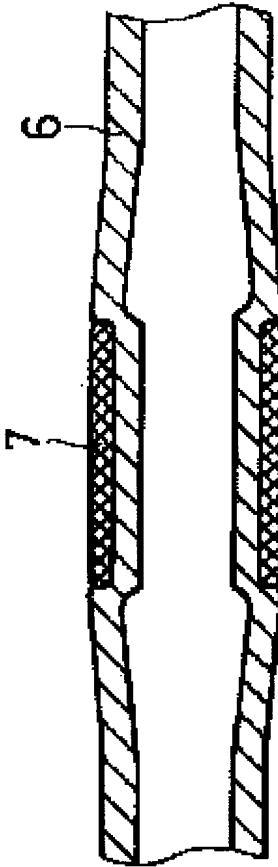
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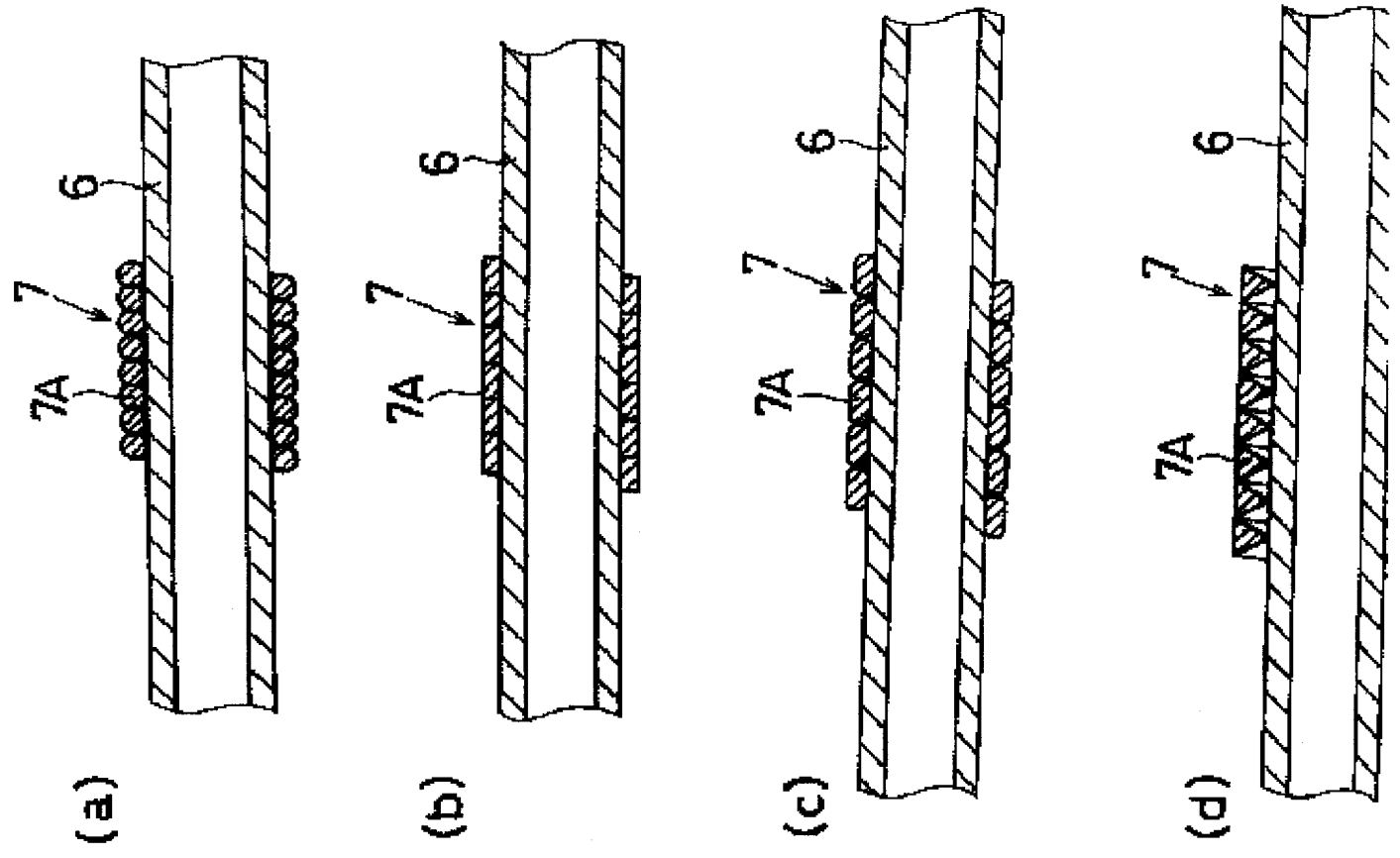




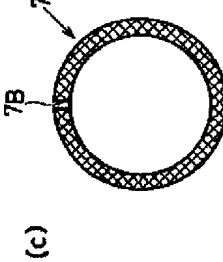
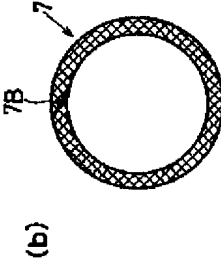
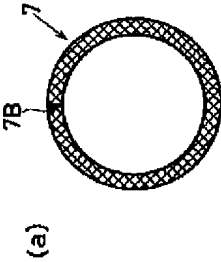






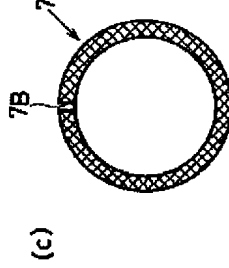
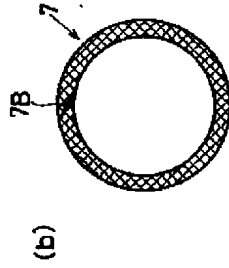
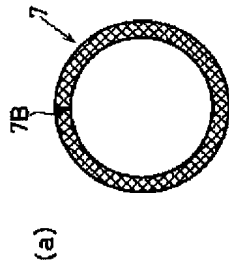


Drawing selection Drawing 13



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Drawing selection Drawing 14



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